1645

PATENT

Attorney Docket No.: 8830-24

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	Patent application of Camilo Anthony Leo Selwyn Colaco	:	
		:	Group Art Unit:
Serial No.:	10/049,702	:	1645
Filed:	April 15, 2002	:	Examiner: Khatol S. Shahnan Shah
For:	STRESS PROTEIN-PEPTIDE COMPLEXES AS VACCINES AGAINST INTRA CELLULAR PATHOGENS	:	

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the office action mailed December 3, 2003. Per the petition and fee submitted herewith, Applicant invokes the benefit of 37 C.F.R. 1.136 to secure a two-month extension of time up to and including March 3, 2004. No further fees are believed due to support the filing of this paper. If an additional fee is due, please charge the same to deposit account 50-0573, and credit any excess to the same account.

CERTIFICATE OF MAILING
UNDER 37 C.F.R. 1.8(a)

I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date indicated below, with sufficient postage, as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

BY Susan Pasuk
Susan Pasuk
DATE: 3/2/04

Response to Restriction Requirement

Applicant provisionally elects, with traverse, Group II (claims 8-11). Reconsideration of the Restriction Requirement in all aspects is requested in view of the following remarks

The present claims are restricted into three groups:

Group I (claims 1-7), drawn to a method for producing a vaccine containing an immunogenic determinant, in which the immunogenic determinant is one or more complexes of stress proteins and antigenic fragments extracted from a cell infected with an intracellular bacterial, protozoan or parasitic pathogen that has been subjected to stress with heat or tumor necrosis factor.

Group II (claims 8-11), drawn to a vaccine containing an immunogenic determinant, in which the immunogenic determinant is one or more complexes of stress proteins and antigenic fragments extracted from a cell infected with an intracellular bacterial, protozoan or parasitic pathogen that has been subjected to stress with heat or tumor necrosis factor.

Group III (claim 12-13), drawn to a method of treating animals with the vaccine of claim 8.

The claims of Groups I, II and III relate, respectively, to a process for making a vaccine, to the vaccine made by the claimed process, and to a method of using the claimed vaccine. For the reasons discussed below, the claims of Groups I, II and III have unity of invention, and should be rejoined for examination on the merits.

The Examiner appears to have subjected the claims to U.S. restriction practice. See, for example, pg. 2 of the Restriction Requirement, where the Examiner states in para. 2, "The inventions are shown to be distinct because they are drawn to distinct methods, which differ in method objectives, method steps, reagents and materials used." The quoted passage represents the U.S., rather than the PCT, standard.

However, the present application represents the U.S. national stage of a PCT application, as filed under 35 U.S.C. § 371. MPEP § 1893.03 states that prosecution of an international application which enters the national stage in the U.S. under 35 U.S.C. § 371(c) "proceeds in the same manner as for a domestic application with the exceptions that . . . (B) unity of invention proceeds as under 37 C.F.R. § 1.475," which is governed by PCT Rule

13. Unity of invention under PCT Rule 13 is satisfied when there is a technical relationship among those inventions defined by the claims which involves "one or more of the same or corresponding special technical features." This unifying special technical feature is that which defines a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. PCT Rule 13.2 and the PCT Administrative Instructions, Annex B, Part 1(b).

Where a single patent application contain claims of different categories, the claims have unity of invention when all claims contain a special technical feature, and the claimed manufacturing process is specifically adapted to produce the claimed product. A process is "specifically adapted" for the manufacture of a claimed product when that process inherently results in the product. PCT Administrative Instructions, Annex B, Part 1(e)(i). According to the PCT Administrative Instructions, Annex B, Part 1(e)(iii), "[t]he words 'specifically adapted' are not intended to imply that the product could not also be manufactured by a different process." Thus, the Examiner need only consider whether claims of different categories contain the same or corresponding special technical feature, and whether the claimed process of manufacture inherently produces the claimed product.

Here, the special technical feature is the immunogenic determinant, which comprises one or more complexes of a heat shock proteins and antigenic peptide fragments derived from a stressed cell infected with an intracellular pathogen. All claims in Groups I, II and III contain this feature. Also, performing the method recited in independent claim 1 necessarily results in the vaccine product of claims 8-11, showing that the Group I methods are "specifically adapted" for producing the claimed vaccine. Thus, the Group I, II and III claims have unity of invention.

The present case is analogous to Example 1 of the PCT Administrative Instructions, Annex B, Part 2(I), which illustrates independent process, product, and method of use claims that have unity of invention. In this Example, three independent claims are given: Claim 1 to a method of manufacturing substance X (represented in the present case by the immunogenic determinant); claim 2 to substance X; and claim 3 to the use of substance X. Unity exists between all three claims because all contain the special technical feature of substance X in common.

The Examiner alleges on pg. 3, para. 2 of the Restriction Requirement that the claims of Groups I and II are "distinct" (and therefore presumably lack unity of invention) because the claimed process can be used to make another materially different product, or the claimed product can be made by another materially different process. However, as discussed above, the fact that the claimed product could perhaps be produced by another method does not prohibit the process of manufacture and product claims from being examined in the same application under PCT Rule 13. There is also no prohibition under PCT Rule 13 against the claimed process being able to produce another product; if the claimed manufacturing process inherently produce the claimed product (and all contain the special technical feature), then the claims have unity of invention. See PCT Administrative Instructions, Annex B, Part 1(e)(iii). Here, the Group I process claims could not produce anything but the vaccine recited in the Group II claims. Since both Group I and II claims possess the same special technical feature, the Group I and II claims have unity of invention.

The Examiner also alleges on pg. 2, para. 2 of the Restriction Requirement that the Group II product claims and Group III method of use claims are "distinct" (and therefore presumably lack unity of invention) because the claimed process of use can be practiced with another materially different product, or the claimed product can be used in another materially different process. However, PCT Rule 13 does not prohibit product and process of use claims from being examined in a single application even if both the claimed product and process can be used separately, in materially different ways. Rather, PCT Rule 13 allows for such claims to be examined together in a single application if all claims contain the same or similar special technical feature. As discussed above, the Group II and III claims all contain the same special technical feature; thus, the Group II and III claims have unity of invention.

Finally, the unity of all claims of the application is further evidenced by the International Search Report dated September 20, 2001 and the International Preliminary Examination Report issued November 26, 2001, where unity of invention among all claims was found.

Because all claims of Groups I, II and III have the same special technical feature, and the claimed product in Group II is inherently made by the claimed Group I process, all pending claims have unity of invention. Applicant requests that the Group I, II and III claims be rejoined for examination on the merits.

Respectfully submitted

CAMILO ANTHONY LEO SELWYN COLACO

BY _____

DANIEL A. MONACO
Reg. No. 30,480
DRINKER, BIDDLE & REATH, LLP.
One Logan Square
18th and Cherry Streets
Philadelphia, PA 19103-6996
(215) 988-3312
(215) 988-2757 – fax
Attorney for the Applicant